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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,742	09/12/2003	Eva Rojer	Strom.7274	9486

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,742	ROJER, EVA	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,32-36,38-40 and 42-44* is/are pending in the application.

4a) Of the above claim(s) *1-30,32-36,38,40 and 42-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 August 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/03 & 8/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

RE: Rojer

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/2009 has been entered.

2. Claims 1-30, 32-36, 38-40 and 42-44 are pending. Claims 31, 37, 41 and 45-50 have been cancelled. Claims 1-30, 32-36, 38, 40 and 42-44 have been withdrawn from consideration. Claim 39 has been amended.

3. Claim 39 is under examination.

Priority

4. A certified copy of the priority document was received on 10/17/2008.

Information Disclosure Statement

5. The reference DE 1974725A1 listed in the information disclosure statements (IDS) filed 9/12/2003 and 8/17/2008 has been considered.

Objection Maintained

6. The objection to the Drawings submitted 8/7/2008 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure is maintained.

The response states that the figure legends and references were included in the PCT application and the figures were also present in the Swedish priority application.

Applicant's arguments have been carefully considered but are not persuasive. Although the figure legends were included in the PCT application, no data (results) were disclosed to be associated with the legends. The figure legends are insufficient to provide support for the results that are disclosed in the drawings. While the foreign priority document disclosed the drawings, MPEP §2163.07 states "Where a foreign priority document under 35 U.S.C. 119 is of record in the U.S. application file, applicant may not rely on the disclosure of that document to support correction of an error in the pending U.S. application. Ex parte Bondiou, 132 USPQ 356 (Bd. App. 1961). This prohibition applies regardless of the language of the foreign priority documents because a claim for priority is simply a claim for the benefit of an earlier filing date for subject matter that is common to two or more applications, and does not serve to incorporate the content of the priority document in the application in which the claim for priority is made". Because of these reasons, the objection is maintained.

Rejections Maintained

Claim Rejections - 35 USC § 112, 1st paragraph

7. The rejection of claim 39 under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting SCCA1 protein or SCCA2 protein in a sample of said human, does not reasonably provide enablement for a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting the SCCA1/SCCA2 fusion protein in a sample of said human is maintained.

The response states that the enclosed experimental data (performed in accordance with those described in the materials and methods section) shows the SCCA1/A2 protein is expressed in SCC cells and not in normal cells and the SCCA1/A2 protein can be detected in SCC cells using the SCC106 antibody.

Applicant's arguments have been carefully considered but are not persuasive. The instant claim requires the monoclonal antibody to have less than 5% cross reactivity for the SCCA1 or SCCA2 antibody (emphasis added). The specification does not teach how to make an antibody that has less than 5% cross reactivity for the SCCA1 or SCCA2 antibody. It appears that applicant intended to say less than 5% cross reactivity for the SCCA1 or SCCA2 antigen (emphasis added). The instant claim recites the term "or" in the phrase "less than 5% cross reactivity for the SCCA1 or SCCA2" (emphasis added), as such the claim encompasses a method for detecting SCCA1/SCCA2 fusion protein using a monoclonal antibody that binds SCCA1/SCCA2 with less than 5% cross reactivity for SCCA2 (it is noted that such antibody could also cross react with SCCA1), or a monoclonal antibody that binds SCCA1/SCCA2 with less than 5% cross reactivity for SCCA1 (such antibody could also cross react with SCCA2).

Because in addition to the fusion protein SCCA1/SCCA2, the recited monoclonal antibody could also bind either SCCA1 or SCCA2, such monoclonal antibody would not specifically detect SCCA1/SCCA2 fusion protein. To specifically detect the SCCA1/SCCA2 fusion protein, one must use a monoclonal antibody specific to SCCA1/SCCA2 fusion protein with less than 5% cross reactivity for both SCCA1 and SCCA2 antigens. However, the specification does not disclose any monoclonal antibodies that bind specifically to the SCCA1/A2 fusion protein with less than 5% cross reactivity for the SCCA1 and SCCA2 antigen. The specification discloses three monoclonal antibodies that bind specifically to SCCA1/A2 fusion protein: SCC106, SCC114 or SCC115 (see the specification, section 5.1). However, all three monoclonal antibodies are shown to have more than 5% cross reactivity to SCCA2 (see Figure 7 of the foreign priority document Sweden 0100938, enclosed as Exhibit A. The Figure 7 of the instant application is not used here because the labels of the drawing are too small to read). Given the extremely high degree of homology of the SCCA1/A2 fusion protein to the SCCA1 and SCCA2 antigens, it is unpredictable one skilled in the art would be able to make an antibody that specifically binds SCCA1/A2 fusion protein with less than 5% cross reactivity for both the SCCA1 and SCCA2 antigens. Although the submitted experimental data shows a protein is expressed in SCC cells and can be detected using the SCC106 antibody, because the SCC106 antibody has about 10% cross reactivity to SCCA2 antigen, one skilled in the art can not exclude the possibility that the protein detected by the SCC106 antibody is the SCCA2 antigen absence evidence to the contrary. For these reasons, the rejection is maintained.

New Grounds of Objections and Rejections

Specification

8. The amendment to the specification filed on 6/4/2007 is objected to because of the following reasons. Applicant inserted "SEQ ID NO:18" to refer to "SCC antigen", and "SEQ ID NO:19" to refer to "different SCC antigens"(see page 4 of the amendment). It is unclear which SCC antigen the added SEQ ID NO is in reference to because SCC antigen may be SCCA1, SCCA2, or a fusion protein thereof. Furthermore, a SEQ ID NO can only be referred to one specific antigen, not multiple antigens. Corrections are required.

9. The sequence listing filed on 6/4/2007 is objected to because the SEQ ID NO:18 and SEQ ID NO:19 included in the sequence listing are considered new matter. Applicant did not point out which proteins the SEQ ID NO:18 and SEQ ID NO:19 are in reference to (see also paragraph 8 above).

If applicant believes that support for the above-mentioned phrases or terms is present in the specification, claims or drawing as originally filed, applicant must, in responding to this action, point out with particularity, where such support may be found.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Cataltepe et al. (Clin. Chim. Acta, 2000, 295:107-127).

Cataltepe et al. teach detection of tumor markers SCCA1 and SCCA2 by immunoassay such as ELISA in plasma samples obtained from patients with squamous cell carcinomas of the head and neck region using a monoclonal antibody that is specific for SCCA1, and a monoclonal antibody that is specific for SCCA2 (see page 119, last paragraph and Figure 6). Cataltepe et al. disclose that the monoclonal antibodies that are specific for SCCA1 have less than 5% cross reactivity to SCCA2, and the monoclonal antibodies that are specific for SCCA2 have less than 5% cross reactivity to SCCA1 (see figure 1 and the abstract). Because Cataltepe et al. teach contacting a sample obtained from a squamous cell carcinoma subject with an antibody that is specific for SCCA1, or SCCA2 protein, and detecting the complex formed between the antibody and the SCCA or SCCA2 protein, and because the antibody of Cataltepe et al. would also bind to the SCCA1/SCCA2 fusion protein (i.e. SEQ ID NO.1), by performing the detection of Cataltepe et al., one would have detected the SCCA1/SCCA2 fusion if the fusion protein was expressed in squamous cell carcinoma as asserted by the instant specification.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
2/25/09